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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/730,796

12/09/2003

Sabine Six

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28501

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10/05/2006

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| EXAMINER |
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ALSTRUM ACEVEDO, JAMES HENRY

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/730,796

Applicant(s)

SIX ET AL.

Examiner

James H. Alstrum-Acevedo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Claims 1-20 are pending.** Receipt and consideration of Applicants' arguments/remarks and amended claims is acknowledged.

#### *Specification*

The objection to the disclosure because of the informalities described on page 2 of the previous office action mailed on January 24, 2006 **is withdrawn**, because Applicants' have corrected said informality.

The objection of claim 8 because of the informalities described on page 2 of the previous office action mailed on January 24, 2006 **is withdrawn**, because Applicants' have corrected said informality.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 1-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, because Applicants' claim amendments have corrected the issues cited on pages 2-3 of the previous office action mailed on January 24, 2006.

#### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-4, 6, 8, 9, and 15 under 35 U.S.C. 102(b) as being anticipated by Keller et al. (WO 00/07567), wherein Keller et al., U. S. Patent No. 6,475,467 was used as the English language equivalent of WO 00/07567, **is withdrawn** per Applicants' claim amendments and persuasive arguments.

The rejection of claims 1-9, 11, 15, and 20 under 35 U.S.C. 102(b) as being anticipated by Jager et al. (U.S. Patent No. 6,045,778) **is maintained** for the reasons of record set forth on pages 6-8 of the previous office action mailed on January 24, 2006.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejections of (1) claims 13, 17, and 19 under 35 U.S.C. 103(a) as being unpatentable over Jager et al. (U.S. Patent No. 6,045,778); (2) claims 10, 12, 14, 16, and 18 under 35 U.S.C. 103(a) as being unpatentable over Jager et al. (U.S. Patent No. 6,045,778) and further in view of Pairet et al. (US 2002/0122773); and (3) claims 1-5, 7-9, 15, and 20 under 35 U.S.C. 103(a) as being unpatentable over Hassan et al. (WO 00/47200) in view of Lewis et al. (US 2002/0025299) **are maintained** for the reasons of record set forth on pages 6-10 (Jager), 10-11 (Jager and Pairet combination), and 11-14 (Hassan and Lewis combination), respectively, of the previous office action mailed on January 24, 2006.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections on the ground of nonstatutory obviousness-type double patenting of (1) claims 1-6 and 8 as being unpatentable over claims 1-6 of copending Application No. 10/392,559 (copending '559); (2) claims 1-6, 8, 9, and 10 as being unpatentable over claims 1-6 of copending Application No. 10/400,127 (copending '127); (3) claims 1 and 10 as being unpatentable over claims 1, 2, and 8 of copending Application No. 10/976,624 (copending '624) in view of *Lewis et al.* (US 2002/0183293); (4) claims 1-3, 15, and 20 as being unpatentable over claims 9, 22-24, 27, and 29 of copending Application No. 10/976,688 (copending '688) in view of *Lewis et al.* (US 2002/0183293); and (5) claims 1-3, 15, and 20 as being unpatentable over claims 12, 21-23, 26, and 28 of copending Application No. 10/977,753 (copending '753) in view of *Lewis et al.* (US 2002/0183293) **are maintained**, because Applicants have decided not to

address these rejections until it has been made clear what subject matter, if any, is deemed patentable by the Examiner.

***Other Matter***

It is noted that there was a typographical error in the previous office action regarding the document number of the Lewis reference used in combination with Hassan (WO 00/47200) in a rejection under 35 U.S.C. §103(a). As Applicants' have asserted, the correct document number for the Lewis reference is US 2002/0025299.

***Response to Arguments***

Applicant's arguments, see pages 6-11, filed July 24, 2006, with respect to the rejection of claims 1-4, 6, 8, 9, and 15 under 35 U.S.C. 102(b) as being anticipated by Keller et al. (WO 00/07567;U. S. Patent No. 6,475,467 was used as the English language equivalent) have been fully considered and are persuasive. The rejection of claims 1-4, 6, 8, 9, and 15 under 35 U.S.C. 102(b) as being anticipated by Keller et al. (WO 00/07567;U. S. Patent No. 6,475,467 was used as the English language equivalent) has been withdrawn.

Applicant's arguments filed July 24, 2006 have been fully considered but they are not persuasive. Applicants' traversal of the rejections relying on Jager (U.S. Patent No. 6,045,778) are based primarily on the allegations that Jager fails to teach (1) the limitation of a pH range of 2.5-4.5 in an aqueous solution as the result of the concentration of an inorganic or an organic acid and (2) a composition comprising tiotropium bromide. As Applicants' have noted, Jager generally states that tiotropium bromide may be used in place of ipratropium bromide (pg. 7 or arguments). In fact, Jager explicitly identifies tiotropium bromide as a preferred medicament

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(col. 4, lines 15-19 and 37-62). It is noted that although a composition comprising tiotropium bromide is not exemplified it is generally accepted that a reference's embodiments are not limiting regarding what is disclosed/taught. Regarding the claimed pH range, Jager discloses in Table 1 an aerosol formulation comprising an inorganic acid (0.01-0.00002 Normal), water (0.0-5% w/w), and other components. The quantity of acid in Table 1 is given in units of normality, which defines a **pH range equivalent to 2.0-4.7** in an aqueous system (col. 6, lines 17-19). It is common knowledge in the art that "normality" is the number of molar equivalents per liter of solution. The acids used by Jager are strong acids and therefore each mole of acid results in one mole of aqueous hydronium acid. As a result the normality range cited by Jager for the inorganic acid present in the composition equivalent to the concentration of acid in units of molarity. It is common knowledge in the art that the calculation of pH based on the concentration of hydronium ions (i.e.  $H^+$  concentration) in units of molarity is accomplished using the following equation:  $pH = -\log [H^+]$ , wherein  $[H^+]$  is the concentration of hydronium ions in units of molarity. Regarding Applicants' traversal of the rejection of claim 10 under 35 U.S.C. §103(a) over Jager in view of Pairet et al. (US 2002/0122773), it is the Examiner's position that because, Jager teaches formulations may comprise 0% water, this obviates the use of anhydrous crystalline tiotropium bromide in compositions comprising tiotropium bromide or its monohydrate.

Applicants' traversal of the rejection of claims 1-5, 7-9, 15, and 20 under 35 U.S.C. 103(a) as being unpatentable over Hassan et al. (WO 00/47200) in view of Lewis et al. (US 2002/0025299) is based on the allegation that the combined prior art teachings lack the teaching of suggestion of the acid limitation of independent claim 1. It appears that Applicants have

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misinterpreted the phrase “apparent pH” in Lewis to mean that the formulations do not have a pH within the range claimed by Applicants and/or that this does not suggest to a skilled artisan that the prior art formulations have such a pH range. Regardless of the source of Applicants’ mistaken assertion, the Examiner respectfully disagrees that the combination of Hassan and Lewis lacks the pH range limitation. Lewis clearly teaches that the formulation have a pH in the range of 3.0-3.5 as the result of the addition of small amounts of hydrochloric acid [0021]. This pH range is within the range claimed by Applicants as set forth in claim 1 of the instant application and therefore obviates Applicants’ claimed pH range.

### ***Conclusion***

**Claims 1-20 are rejected. No claims are allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

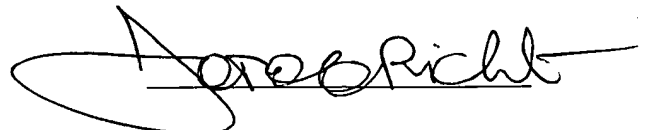


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.  
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A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning.

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